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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,021	03/16/2001	Hubert Metzner	06478.1452	5147

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EXAMINER

MELLER, MICHAEL V

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

*1*

Application Number: 09/809,021  
Filing Date: March 16, 2001  
Appellant(s): METZNER ET AL.

\_\_\_\_\_  
Carol Einaudi  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 5/19/2004.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

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**(6) Issues**

The appellant's statement of the issues in the brief is correct.

**(7) Grouping of Claims**

Appellant's brief includes a statement that claims 18-19 and 35-38 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

4,363,319	Altshuler	12-1982
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5,945,103	Hanada et al.	8/1999
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Allary et al., Annales Pharmaceutiques Francaises, 1990, vol. 48, no.3, pgs. 129-135.

Lorne et al., Rev. Fr. Transfus. Hemobiol., 1989, 32, pgs. 391-400.

Brezniak et al., Blood Coagulation and Fibrinolysis, 1994, vol. 5, pgs. 847-848.

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 18, 35, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Allary et al. (abstract) or Lorne et al. (abstract).

The references each teach that thrombin is eluted off a benzamidine-Sepharose column. Thrombin and benzamidin would be together in the eluate. Since they elute using benzamidine in a competitive elution then a complex of thrombin-benzamidine as in the present claims would have been formed.

Claims 18, 19 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allary et al. or Lorne et al . taken with Hanada et al., Brezniak et al. and Altshuler.

The teachings of Allary and Lorne are above.

Allary and Lorne do not teach using the other ingredients in the composition such as lysine, calcium chloride, NaCl, etc.

Hanada teaches that thrombin can be therapeutically viable using many of the other components in the composition and that p-aminobenzamidine and benzamidine are interchangeable, see all of col. 4. Altshuler teaches that therapeutically viable thrombin can also include other components in the composition such as lysine, NaCl, glycerol, see col. 3, lines 13-30, example I. Brezniak also teaches that therapeutically viable thrombin can include other ingredients in the composition such as calcium chloride, polyethylene glycol, NaCl, see abstract, page 847.

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Thus, it would have been obvious to add the other components (NaCl, lysine, glycerol, calcium chloride, etc.) to the composition of thrombin and benzamidine of Allary and Lorne since it is well known in the art as is established by Altshuler, Brezniak and Hanada that the other components are well known to be added to therapeutically viable compositions of thrombin.

**(11) *Response to Argument***

Appellant argues that the preparations disclosed in Allary et al. and Lorne et al. are not "suitable for therapeutic purposes". Appellant argues that the chromatography used will yield preparations which have "unsuitable run-off" from the columns, but appellant also uses columns in the making of their thrombin preparation which would also have "unsuitable run-off". Thus, appellant is making the preparation the same way as the references are, thus the products are the thrombin preparations are the same in the references and that of appellant. Further, there is no definition in appellant's specification of what "suitable for therapeutic purposes" actually means. The references clearly teach thrombin preparations which are going to be used for suitable therapeutic purposes, namely as a biological glue. Thus, the claims are clearly anticipated by the references. Appellant has shown no evidence of why the references yield thrombin-benzamidine compositions which are "unsuitable for therapeutic purposes".

Appellants argue that Hanada also teaches thrombin preparations that are “unsuitable for therapeutic purposes”, but this reference was only used as a secondary reference for motivation to add the other ingredients into the thrombin-benzamidine preparation such as glycine, NaCl, etc. The same is true for the Brezniak and Altshuler references. Appellant argues that Brezniak teaches away from the invention by suggesting that calcium chloride is not an effective thrombin stabilizer. While Brezniak may state this they are not saying that the calcium chloride is not useful. In fact, in the abstract they still state the use of calcium chloride. One can still use both calcium chloride and NaCl in the composition as claimed. Appellant next argues that Alshuler only teaches using dry or powdered compositions but appellant’s own claims do not state what form their preparation is in. In fact, even claim 19 does not require that the state of the composition be definite, thus whether Altshuler mentions the state of the calcium chloride as dry or aqueous does not really matter since the claims never require that the state of the calcium chloride be definite.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Michael V. Meller  
Primary Examiner  
Art Unit 1654

MVM

July 6, 2004

Conferees:

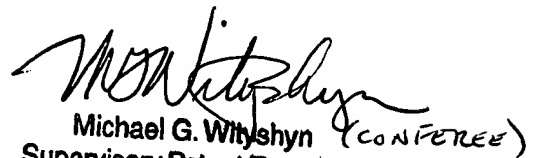
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